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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,823	10/23/2003	David Grewe	CRD1061CIP1	6328

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EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT	PAPER NUMBER
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3736

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

6D

Office Action Summary	Application No. 10/691,823	Applicant(s) GREWE ET AL.	
	Examiner Jeffrey G. Hoekstra	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-19,21-23 and 25-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-19,21-23 and 25-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice of Amendment

1. In response to the amendment filed on 12/29/2006, amended claim(s) 1, 3, 19, 21, 23, and 25 and canceled claim(s) 2, 20, and 24 is/are acknowledged. The current rejections of the claim(s) 1, 3-19, 21-23, and 25-39 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayzelden et al (US 2002/0165534 A1) in view of Klima et al (US 6,273,876 B1) as broadly as *structurally* claimed.

4. For claims 1, 3, 4, 19, 21-23, 25, and 26, Hayzelden et al teaches a bi-directional steerable guidewire, an intravascular device, having a deflectable tip, comprising:

- an elongated flexible tubing (22) defining a lumen (28) member having proximal (26) and distal portions (24);
- a flexible helical coil (82) having multiple turns and having proximal and distal ends (as best seen in Figures 2 and 3);
- an elongated deflection member (124 and 56) having proximal and distal portions and being slidably disposed within said tubing and within said helical coil (as best

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seen in Figures 5 and 8), the proximal portion of the deflection member being of a cylindrical cross section and the distal portion of said deflection member being flattened to form a deflection ribbon which extends in a plane (paragraph 43);

- a retaining ribbon (54) having proximal and distal ends, the proximal end of the retaining ribbon is attached to the distal portion of the flexible tubing and the retaining ribbon is oriented to extend in a plane which is generally parallel to the plane of the deflection ribbon; and
- an attachment member (50), a rounded bead, engaging the distal end of the helical coil, the distal portion of the deflection member and the distal end of the retaining ribbon so that longitudinal movement of the deflection member in a distal direction causes the distal end of the helical coil to be deflected in one direction and longitudinal movement of the deflection member in a proximal direction causes the distal end of the helical coil to deflect in another opposite direction (as best seen in Figure 2).

5. For claims 5 and 27, Hayzelden et al discloses a bi-directional steerable guidewire having a deflectable tip, wherein the retaining ribbon and the deflection ribbon are capable of being normally biased in an arcuate configuration causing the distal end of the helical coil to be normally biased in a curved shape due to being a shape-memory metallic alloy (Hayzelden et al, paragraph 43).

6. For claims 6 and 28, Hayzelden et al discloses a bi-directional steerable guidewire having a deflectable tip, wherein the proximal portion of said deflection member is capable of being a circular cross section that extends from the proximal

portion of the flexible tubing to approximately the distal portion of the tubing by not being entirely flattened (Hayzelden et al, paragraph 43).

7. For claim 7, Hayzelden et al discloses a bi-directional steerable guidewire having a deflectable tip, wherein the proximal end of said retaining ribbon extends from the distal portion of the flexible tubing to approximately the distal end of the flexible helical coil (Hayzelden et al, Figure 1).

8. For claim 8, Hayzelden et al discloses a bi-directional steerable guidewire having a deflectable tip, wherein the attachment member takes the form of a rounded bead (50).

9. For claim 9, Hayzelden et al discloses a bi-directional steerable guidewire having a deflectable tip, wherein the rounded bead is formed with an epoxy material (Hayzelden et al, paragraph 30).

10. For claims 10 and 29, Hayzelden et al discloses a bi-directional steerable guidewire having a deflectable tip, wherein the attachment member takes the form of a rounded bead (50) which contacts the distal end of the helical coil to define a circular surface at the distal end of the coil and the deflection ribbon (56) engages the rounded bead at a location offset from the center of the circular surface of the rounded bead (Hayzelden et al, Figures 6 and 10).

11. For claims 11 and 30, Hayzelden et al discloses a bi-directional steerable guidewire having a deflectable tip, wherein the distal end of the retaining ribbon engages the rounded bead at a location offset from the center of the circular surface of the rounded bead (Hayzelden et al, Figures 6 and 10).

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12. For claims 12 and 31, Hayzelden et al discloses a bi-directional steerable guidewire having a deflectable tip, wherein the distal end of the retaining ribbon engages the rounded bead at a location offset from the center of the circular surface in an opposite direction from the offset location of the deflection ribbon (Hayzelden et al, Figure 6).

13. For claims 13 and 32, Hayzelden et al discloses s a bi-directional steerable guidewire having a deflectable tip, wherein the deflection member and the retaining ribbon are joined to each other within the rounded bead (Hayzelden et al, Figures 2 and 5).

14. For claim 14, Hayzelden et al discloses a bi-directional steerable guidewire having a deflectable tip, wherein the deflection ribbon and the retaining ribbon are formed as a single unitary element (54).

15. For claims 15 and 33, Hayzelden et al discloses a bi-directional steerable guidewire having a deflectable tip, wherein the deflection ribbon and the retaining ribbon are joined to form a generally U-shaped configuration (54) to thereby provide a predetermined spacing between the deflection ribbon and the retaining ribbon and to maintain the deflection ribbon and the retaining ribbon in planes which are parallel to each other (Hayzelden et al, Figures 2, 5 and 6).

16. For claims 16 and 34, Hayzelden et al discloses a bi-directional steerable guidewire having a deflectable tip, wherein the deflection ribbon is formed by flattening an intermediate portion of the deflection member and the retaining ribbon is formed by flattening a distal portion of the deflection member (Hayzelden et al, paragraph 43).

17. For claims 17 and 35, Hayzelden et al discloses a bi-directional steerable guidewire having a deflectable tip, wherein the retaining ribbon is capable of having a thickness that is less than the thickness of the deflection ribbon via extra flattening (Hayzelden et al, paragraph 43).

18. For claim 18, Hayzelden et al discloses a bi-directional steerable guidewire having a deflectable tip, wherein the deflection ribbon is capable of having a thickness of .002 inches and the retaining ribbon is of a thickness of .0015 inches.

19. For claim 36, Hayzelden et al discloses a bi-directional steerable guidewire having a deflectable tip, wherein the proximal portion of the elongated flexible tubing is coupled to a control handle (42) and the elongated deflection member is mounted with the control handle for longitudinal movement (Hayzelden et al, Figure 1).

For claim 37, Hayzelden et al discloses a bi-directional steerable guidewire having a deflectable tip, wherein said control handle includes a movable knob (78) that is coupled to the elongated deflection member for longitudinal positioning of the deflection member.

20. Thus, Hayzelden et al discloses the claimed invention except for explicitly disclosing the helical coil having a rectangular cross-sectional configuration and having continuous undulations, wherein the undulations of adjacent turns interlock with each other in order to enhance the rotational rigidity of the coil and wherein the undulations take the form of a sinusoidal wave and a square sinusoidal wave having positive and negative peaks and in which the positive peaks of adjacent turns of coils engage negative peaks of adjacent turns; wherein the helical coil has a square cross-sectional

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configuration; the proximal end of said helical coil is attached to the distal portion of the flexible tubing; and wherein said undulations are lateral to the length of the elongated flexible tubing. Klima et al teaches a catheter, an intravascular device, having a helical coil (72i) having a rectangular cross-sectional configuration and having continuous undulations wherein the undulations of adjacent turns interlock with each other in order to enhance the rotational rigidity of the coil and wherein the undulations take the form of a sinusoidal wave (as best seen in Figures 11A, 11B, 12A, 12B and 15) and a square sinusoidal wave (as best seen in Figures 13A, 13B, and 15) having positive and negative peaks (created by fingers 1077) and in which the positive peaks of adjacent turns of coils engage negative peaks of adjacent turns (column 11 lines 26-30); wherein the helical coil has a square cross-sectional configuration; the proximal end of said helical coil is attached to the distal portion of the flexible tubing; and wherein said undulations are lateral to the length of the elongated flexible tubing (column 10 lines 25-58 and as best seen in Figures 13B and 15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the intravascular device as taught by Hayzelden et al, with the helical coil configuration as taught by Klima et al for the purpose of increasing the efficacy of an intravascular device to navigate tortuous vasculature.

21. Claims 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayzelden et al in view of Klima et al and in further view of Palermo (US 4,886,067) as broadly as structurally claimed. Hayzelden et al in view of Klima et al

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discloses the claimed invention except for explicitly disclosing the control handle coupled to the elongated flexible tubing with a release mechanism and the elongated deflection member extending through the entire length of the control handle and beyond the proximal end of the control handle. Palermo teaches an intravascular device (12) with a control handle (53) coupled to the elongated flexible tubing with a release mechanism (70) and an elongated deflection member (44) extending through the entire length of the control handle and beyond the proximal end of the control handle (as best seen in Figure 4). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the intravascular device as taught by Hayzelden et al in view of Klima et al, with the handle configuration as taught by Palermo for the purpose of increasing the efficacy of an intravascular device to navigate tortuous vasculature.

Response to Arguments

22. Applicant's arguments filed 12/29/06 have been fully considered but they are not persuasive. Applicant argues (a) Hayzelden does not teach a "bi-directional steerable guidewire"; (b) Hayzelden et al does not teach a "flexible helical coil"; (c) Hayzelden et al does not teach a "retaining ribbon"; (d) Hayzelden et al does not teach a "rounded bead"; and (e) Klima et al teaches away from having positive and negative peaks. The Examiner disagrees, maintains the 103 rejection, and notes the following:

23. In response to applicant's arguments, (a)-(e), against the references individually, one cannot show nonobviousness by attacking references individually where the

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rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Nonetheless, the Examiner notes the following:

24. In response to applicant's arguments (a), the recitation of a "bi-directional steerable guidewire" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

25. In response to applicant's arguments (b)-(d), as broadly as structurally claimed the cited elements of Hayzelden et al in view of Klima et al meet the claimed limitations as stated above.

26. In response to applicant's arguments (e), as broadly as structurally claimed the cited elements of Hayzelden et al in view of Klima et al meet the claimed limitations as stated above.

Conclusion

27. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571) 272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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